September 28, 2005

Mr. Gregg R. Overbeck
Senior Vice President, Nuclear
Arizona Public Service Company
P. O. Box 52034
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SUBJECT: PALO VERDE NUCLEAR GENERATING STATION, UNITS 1, 2, AND 3 - APPROVAL OF CHANGE TO QUALITY ASSURANCE PROGRAM (COMMERCIAL-GRADE CALIBRATION SERVICES) (TAC NOS. MC4402, MC4403, AND MC4404)

Dear Mr. Overbeck:

By letter dated September 5, 2004, Arizona Public Service Company (the licensee) submitted a proposed change to the Quality Assurance (QA) Program for the Palo Verde Nuclear Generating Station, Units 1, 2, and 3 for Nuclear Regulatory Commission (NRC) review and approval in accordance with the regulation in Paragraph 50.54(a)(4) of Title 10 of the *Code of Federal Regulations* (10 CFR). The proposed change would provide for acceptance of accreditation of commercial-grade calibration services by a nationally-recognized accrediting body, using procedures consistent with international standards and guidelines, specifically those found in ANSI/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." The accreditation process would be credited in lieu of a supplier audit, commercial-grade survey, or in-process surveillance. This method for qualifying the calibration supplier and accepting its calibration services would be applied only to commercial-grade calibration services as defined by 10 CFR Part 21.

The enclosed safety evaluation documents the NRC staff's conclusion that changes to the QA Program and the reviewed positions with respect to applicable regulatory guides and standards, described in Section 17.2B of the licensee's Updated Final Safety Analysis Report, continues to satisfy the requirements of Appendix B to 10 CFR Part 50 and, therefore, is acceptable.

If you have any questions, please contact Mel Fields at (301) 415-3062.

Sincerely,

/RA/

Daniel S. Collins, Acting Chief, Section 2
Project Directorate IV
Division of Licensing Project Management
Office of Nuclear Reactor Regulation

Docket Nos. STN 50-528, STN 50-529,
and STN 50-530

Enclosure: Safety Evaluation

cc w/encl: See next page

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The enclosed safety evaluation documents the NRC staff's conclusion that changes to the QA Program and the reviewed positions with respect to applicable regulatory guides and standards, described in Section 17.2B of the licensee's Updated Final Safety Analysis Report, continues to satisfy the requirements of Appendix B to 10 CFR Part 50 and, therefore, is acceptable.

If you have any questions, please contact Mel Fields at (301) 415-3062.

Sincerely,
/RA/
Daniel S. Collins, Acting Chief, Section 2
Project Directorate IV
Division of Licensing Project Management
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Docket Nos. STN 50-528, STN 50-529,
and STN 50-530

Enclosure: Safety Evaluation

cc w/encl: See next page

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SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

PROPOSED CHANGE TO THE QUALITY ASSURANCE PROGRAM

COMMERCIAL-GRADE CALIBRATION SERVICES

ARIZONA PUBLIC SERVICE COMPANY, ET AL.

PALO VERDE NUCLEAR GENERATING STATION, UNITS 1, 2, AND 3

DOCKET NOS. 50-528, 50-529, AND 50-530

1.0 INTRODUCTION

By letter dated September 5, 2004 (Reference 1), Arizona Public Service Company (APS, the licensee) submitted a proposed change to the quality assurance (QA) Program for the Palo Verde Nuclear Generating Station (PVNGS), Units 1, 2, and 3 for Nuclear Regulatory Commission (NRC) review and approval in accordance with the regulation in Paragraph 50.54(a)(4) of Title 10 of the *Code of Federal Regulations* (10 CFR). The proposed change would provide for acceptance of accreditation of commercial-grade calibration services by a nationally-recognized accrediting body, using procedures consistent with international standards and guidelines, specifically those found in ANSI/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." The accreditation process would be credited in lieu of a supplier audit, commercial-grade survey, or in-process surveillance. This method for qualifying the calibration supplier and accepting its calibration services would be applied only to commercial-grade calibration services as defined by 10 CFR Part 21.

2.0 REGULATORY EVALUATION

The licensee's QA Program for operation and maintenance of the PVNGS, Units 1, 2, and 3 is described in Chapter 17.2 of the Updated Final Safety Analysis Report (UFSAR). Section 17.2B of the UFSAR identifies the regulatory guides and standards to which the licensee has committed in implementing the requirements of Appendix B to 10 CFR Part 50. The predominant criteria of Appendix B that are related to the proposed QA Program change and which may be affected are Criteria 1, 4, 7, 12, and 18.

Criterion 1, "Organization," allows for the delegation of authorities and duties for carrying out portions of the QA Program to others. Delegation of commercial-grade services would be controlled through procurement documents and purchasing requirements. The portion of the QA process, specifically that of qualifying the supplier, would be clearly established and delineated in the QA Program.

Criterion 4, "Procurement Document Control," requires that measures be established to assure that applicable regulatory requirements, design bases, and other requirements necessary to assure quality are stipulated or referenced in procurement documents. The licensee would

continue to impose the pertinent requirements of 10 CFR Part 50, Appendix B on approved and accredited suppliers of commercial-grade calibration services. However, the methods and criteria for evaluating and selecting suppliers would be based on ANSI/ISO/IEC 17025, as implemented by recognized internationally accrediting bodies.

Criterion 7, "Control of Purchased Material, Equipment, and Services," requires that measures be established to assure that purchased material, equipment, and services conform to the procurement documents. In the case of commercial-grade calibration services, the licensee or licensee-approved Appendix B suppliers, would be responsible for reviewing objective evidence for conformance to the procurement documents. The licensee would be required to verify the commercial-grade supplier's accreditation and to assure that the scope of accreditation covers the needed measurement parameters, ranges, and uncertainties.

Criterion 12, "Control of Measuring and Test Equipment," requires that measures be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits. The licensee would specify through procurement documents that as-found calibration data be provided when the item being calibrated is found out-of-tolerance.

Criterion 18, "Audits," requires that a comprehensive system of planned and periodic audits be carried out by appropriately trained personnel not having direct responsibility in the areas being audited. The licensee proposes an alternative to the regulatory guidance that would allow the acceptance of accreditation in lieu of audits by the purchasers or their representatives (e.g., Nuclear Procurement Issues Committee (NUPIC)). The accreditation process would provide a level of confidence that applicable elements of the calibration QA Program have been developed, documented, and effectively implemented in accordance with the specified requirements.

When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, a commercial-grade item (CGI) means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. A basic component is an item that is designed and manufactured under a QA Program complying with 10 CFR Part 50 (or CGIs which have successfully completed the dedication process). For CGIs, 10 CFR Part 21 also defines critical characteristics, which are those important design, material, and performance characteristics that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Electric Power Research Institute (EPRI) report NP-5652 (Reference 2) describes generic methodologies for procuring and accepting commercial-grade items. Two distinct processes are involved: (1) technical evaluation to ensure that all necessary requirements are specified in the procurement document and (2) acceptance method that provides assurance that the item is adequate to meet the requirements of 10 CFR Part 50, Appendix B. Four acceptance methods are described in NP-5652 and are conditionally endorsed by NRC Generic Letter 89-02 (Reference 3).

Critical characteristics are developed as part of the technical evaluation. Acceptance methods include source verifications and CGI surveys. Source verifications inspect and verify those critical characteristics that can only be verified at a supplier's facility. CGI surveys are

conducted to ensure that the CGI supplier's commercial QA Program and processes are adequate to provide reasonable assurance that the specified critical characteristics will be maintained in the item. For the proposed alternative, the licensee would specify the critical characteristics through the procurement documents.

3.0 TECHNICAL EVALUATION

The licensee proposes that accreditation by a nationally-recognized accrediting body, specifically the National Voluntary Laboratory Accreditation Program (NVLAP), be accepted in lieu of a supplier audit, commercial-grade survey, or in-process surveillance during performance of the accredited calibration services. The licensee further proposes that accreditation by an accrediting body recognized by NVLAP via a Mutual Recognition Arrangement (MRA) be acceptable.

3.1 Background (Laboratory Accreditation)

In evaluating the proposed alternatives, the NRC staff examined the NVLAP accreditation program, administered by the National Institute of Standards and Technology (NIST), and the accreditation program administered by the American Association for Laboratory Accreditation (A2LA). Both accreditation bodies are signatories to the International Laboratory Accreditation Cooperation (ILAC). ILAC is the world's principal forum for the development of laboratory practices, the promotion of laboratory accreditation, the assistance of developing accreditation systems, and the recognition of competent test facilities.

ILAC was formalized as a cooperative agreement in 1996 by a memorandum of understanding signed by 44 national bodies. In 2002, 36 laboratory accreditation bodies, (ILAC full members) signed an MRA to promote the acceptance of accredited technical test and calibration data worldwide. The signatories have been evaluated by their peers (against the acceptance criteria of ISO/IEC Guide 58, "Calibration and Testing Laboratory Accreditation Systems - General Requirements for Operation and Recognition") and have demonstrated that they meet ILAC criteria for competence. Periodic reevaluations are conducted to maintain ILAC recognition. ILAC MRA documentation, including requirements for evaluation of accrediting bodies, is publically available on the ILAC website.

NVLAP provides third-party accreditation services to public and private calibration laboratories based on evaluation of their technical qualifications and competence to carry out specific calibrations. Accreditation criteria are established in accordance with 15 CFR Part 285, "NVLAP Procedures and General Requirements," and encompass the requirements of ANSI/ISO/IEC 17025. The accreditation is formalized through issuance of a Certificate of Accreditation and Scope of Accreditation. NVLAP specifically recognizes the equivalency of the A2LA accreditation process through the ILAC MRA.

A2LA also provides third-party accreditation services to public and private calibration laboratories. A2LA is a nonprofit, nongovernmental, public service, membership society. A2LA provides comprehensive services in laboratory accreditation and laboratory-related training. Accreditation criteria encompass the requirements of ANSI/ISO/IEC 17025. The accreditation is formalized through issuance of a Certificate of Accreditation and Scope of Accreditation.

3.2 Evaluation of NVLAP Accreditation

The NRC staff's evaluation of NVLAP included an assessment of the program's internal administrative process, comparison of the NVLAP and NUPIC supplier evaluation processes, and observation of an NVLAP accreditation assessment.

3.2.1 NVLAP Program Administration

The NRC and NVLAP staffs met on several occasions to discuss the NVLAP program specifics and to review internal program documentation and files. From the list of scheduled laboratory accreditation assessments, the NRC staff selected an assessment to observe and to serve as a basis for evaluating programmatic requirements. Records of past assessments for the selected laboratory were pulled from the files and examined for adequacy and completeness. Corrective action documentation related to deficiencies identified during these assessments were reviewed and found to be complete. Assessor training, qualification, and periodic evaluation documentation were evaluated and the files were found to be adequately maintained in accordance with administrative requirements.

Internal audits, conducted against ISO/IEC Guide 58 to assess the effectiveness of the NVLAP program, were reviewed and discussed with audit personnel. The most recent NVLAP internal audit, conducted from January 31 to April 7, 2005, was structured to determine the extent of NVLAP's compliance with the international standard for accrediting bodies, ISO/IEC 17011:2004, "Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies, and to identify opportunities for improvement of its management system." The internal audit report (IA-2005-01) was reviewed in detail and discussed with the NVLAP audit team leader. The audit identified a few administrative deficiencies of a minor nature, but concluded that NVLAP program essentially conforms with ISO/IEC 17011:2004.

3.2.2 Comparison of Survey Methods

Surveys of suppliers of CGIs and services are generally performed by audit personnel from the licensee's organization or by NUPIC, an industry-wide program for evaluation of suppliers. NUPIC audits and surveys are performed in accordance with a standardized industry-wide approach and conducted by teams composed of utility audit personnel and technical specialists. For commercial-grade surveys of calibration services, a standardized guideline (Reference 4) and a checklist (Reference 5) are used. The methodology is consistent with the philosophy and principles of EPRI report NP-5652.

Technical and general requirements supplemental to the NVLAP program established in accordance with 15 CFR Part 285 are provided in handbooks and documents. NIST Handbook 150 (Reference 6), Sections 4 and 5 contain general requirements that laboratories must meet to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results. The managerial and technical requirements of ISO/IEC 17025 are contained in their entirety in Section 4 and 5 of the NIST handbook.

A comparative evaluation of the commercial-grade survey methodology used by the nuclear industry against the requirements of ANSI/ISO/IEC 17025 is reported in NISTIR 6989

(Reference 7). Based on a line item comparison of the NUPIC checklist with ANSI/ISO/IEC 17025, the report concludes that ANSI/ISO/IEC 17025 addresses all but two administrative requirements, namely:

1. NUPIC clause 14.1.c.7 "The calibration certificate/report shall include identification of the laboratory equipment/standards used." ANSI/ISO/IEC 17025 does not require that this information be reported.

2. NUPIC clause 14.1.c.12 "The calibration certificate/report shall include as-found and as-left data." ANSI/ISO/IEC 17025 does not require as-found data to be reported unless the device under test is adjusted/repaired.

One additional conclusion in methodology is discussed in the report. Clause 4.1 of the NUPIC checklist states, in part, "Well defined and documented measurement assurance techniques or uncertainty analyses may be used to verify the adequacy of the measurement process. If such techniques are not used, the collective uncertainty of the measurement standards shall not exceed 25% of the acceptable tolerance for each characteristic being calibrated." (This is typically referred to as the four-to-one ratio.) Since ANSI/ISO/IEC 17025 requires an uncertainty analysis, the alternate "four-to-one" provision does not apply.

These issues are discussed further in Section 3.4.2 of this evaluation.

3.2.3 Observation of Survey Performance

To compare the NVLAP and NUPIC assessment processes, the NRC staff selected an NVLAP accreditation assessment at the General Electric Infrastructure Sensors (GEIS) Laboratory (formerly Ruska Instrument Corporation) in Houston, Texas and a NUPIC commercial-grade survey at Wilcoxon Research in Gaithersburg, Maryland. GEIS Laboratory is a manufacturer of precision laboratory instrumentation, offering primary pressure standards and pressure calibration services. Wilcoxon Research is a manufacturer of vibration sensors and sensor calibration services.

The NVLAP assessment at GEIS Laboratory was conducted from March 29 to 30, 2005, for the purpose of continued accreditation (NVLAP Lab Code 200491-0) for the fields of Mechanical and Thermodynamics primary and secondary piston gauge masses. The assessment was performed in accordance with NVLAP Handbook 150, ANSI Z 540-Part 1, and ISO 17025-2000. The assessment report (Reference 8) concluded that the laboratory is competent, qualified, and recommended continued accreditation. Continued accreditation was granted, effective April 8, 2005.

The NUPIC survey at Wilcoxon was conducted from July 12 to 14, 2005, for the purpose of evaluating the adequacy and implementation of the Wilcoxon QA Program as described in the Wilcoxon Quality Assurance Manual 402 003, Revision H, dated June 28, 2004. The assessment was performed in accordance with References 4 and 5. The survey report concluded that the supplier's QA Program was effectively implemented, with the exception of findings identified in the report (Reference 9). The findings are followed by the lead utility's corrective action program through resolution. The survey report, checklist, findings, survey

plan, and associated documents are maintained on a password-protected database and available to the NUPIC membership as a basis for placing Wilcoxon Research on a utility's approved supplier list.

The NRC staff's comparative evaluation of the NUPIC and NVLAP processes included review of previous evaluations of the subject suppliers, participation in pre-assessment activities, entrance and exit meetings, team meetings, observation of all assessment activities, and review of the assessment reports and corrective actions. The NRC staff found both the NUPIC and NVLAP assessments to be well planned, executed, and accurately reported. The members of both survey teams were technically competent and the surveys were conducted in a professional manner. All administrative and technical requirements of the checklists discussed in Section 3.2.1 above were comprehensively addressed. Nonconformances with checklist items were adequately characterized to the supplier and documented in the survey report. The NRC staff found the performance of the observed NVLAP assessment to be administratively and technically equivalent to that of the NUPIC survey.

3.3 Evaluation of A2LA Accreditation

A2LA is a nonprofit, nongovernmental, public service organization founded in 1978. A2LA currently provides accreditation for more than 400 laboratories, including approximately 29 of which are international. A2LA and NVLAP are signatory members of the ILAC. The NRC staff evaluated the adequacy of A2LA as an alternative to the NUPIC process, on the basis of NVLAP's recognition of A2LA through the ILAC MRA.

The A2LA website provides extensive information on the A2LA accreditation process, including programmatic documents, such as A2LA calibration program requirements, and identification, status, and scope of accredited laboratory programs. A2LA is governed by a Board of Directors, independent of the A2LA staff, and representing interests of the industry, labor, laboratories, government, and professions. An Accreditation Council, composed of representative stakeholders, makes decisions concerning granting, denying, or withdrawing accreditation, based on assessment documentation provided by A2LA assessors and the laboratory response to any deficiencies cited. Accreditation criteria are reviewed and approved by a Criteria Council, representative of stakeholder interests and include the requirements of ANSI/ISO/IEC 17025.

Advisory committees are set up for certain fields or program areas where technical advice is needed beyond that which can be obtained from existing consensus standards and industry committees. These committees provide advice on the development of program requirements and the interpretation and/or amplification of ANSI/ISO/IEC 17025 requirements for particular fields. Reports of the advisory committees are reported to the Criteria Council.

The NRC staff met with A2LA staff on July 21, 2005, with managers representing all A2LA functions in attendance. The A2LA staff presented an overview of the A2LA accreditation process and responded knowledgeably and openly to NRC's questions. The purpose of this meeting was to discuss information already publically available and no new information considered significant to the NRC was presented during this meeting. The NRC staff found the A2LA administrative and accreditation processes to be very similar to the NVLAP processes, which had been previously evaluated. The NRC was invited to observe future A2LA accreditation assessments and evaluations of the A2LA program conducted by ILAC

membership in accordance with ISO/IEC Guide 58. The NRC learned that A2LA assessors, including an assessor that participated in the observed NVLAP assessment, are drawn from the same general population of assessors that conduct the NVLAP assessments.

The NRC staff also reviewed A2LA program documentation and internal documents related to assessor qualifications, oversight, guidance, and on-site evaluation.

Based on the similarity of the A2LA and NVLAP accreditation processes, the meeting with the A2LA staff, review of publically available and internal administrative procedures, the openness and completeness of A2LA responses to NRC's questions, and the open invitation to participate in future A2LA accreditation assessments, and ILAC assessments of the A2LA program; the NRC staff found the A2LA process to be an acceptable alternative to the methods currently used by licensees to qualify suppliers. Continued acceptability of the A2LA alternative is contingent on NVLAP recognition through the ILAC MRA.

3.4 Licensee QA Program Commitments and NRC Bases for Acceptance

The licensee's operational QA Program is described in Section 17.2 of the PVNGS UFSAR, Revision 12. The scope of the proposed changes is limited to procurement of commercial-grade calibration services. Qualification and selection processes for external organizations are addressed in Section 17.2.3.3.2 of the licensee's QA Program. The proposed alternative for qualifying suppliers involves changes to current commitments to regulatory guides addressed in UFSAR, Section 1.8.

3.4.1 Regulatory Guide 1.33

Regulatory Guide (RG) 1.33 (Reference 10) describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to overall quality assurance requirements for the operation phase of nuclear power plants. RG 1.33, Revision 2 conditionally endorses ANSI N18.7-1976/ANS-3.2, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants," which incorporates other standards by reference.

With respect to RG 1.33, position C.2, the licensee proposes the following clarification:

> Compliance with ANSI standards referenced throughout ANSI N18.7-1976/ANS-3.2 (N18.7) is addressed separately in APS' response to conformance with the regulatory guides listed in section C.2 of Regulatory Guide 1.33.

The NRC staff finds the clarification acceptable in that it refers to conformance statements made elsewhere in Section 1.8, which are reviewed by the NRC staff on a case-by-case basis.

Position C.2 of RG 1.33 identifies ANSI N45.2, "Quality Assurance Program Requirements for Nuclear Facilities," as incorporated by reference by ANSI N18.7. With respect to ANSI N18.7, the licensee proposes to take the following exception:

> When purchasing commercial-grade calibration services from certain accredited calibration laboratories, the procurement documents are not required to impose a quality

assurance program consistent with ANSI N45.2-1971. Alternative requirements described in UFSAR Section 1.8 for Regulatory Guide 1.123 may be implemented in lieu of imposing a quality assurance program consistent with ANSI N45.2-1971.

The NRC staff finds the exception acceptable on the basis of its review of the NVLAP and A2LA accreditation processes and the alternative requirements identified in Section 3.4.2 below.

3.4.2 Regulatory Guide 1.123

RG 1.123 (Reference 11) describes a method acceptable to the NRC staff for complying with the Commission's requirements for control of procurement of items and services during the design, construction, and operations phases of nuclear power plants. RG 1.123, Revision 1 conditionally endorses ANSI N45.2.13-1976, "Quality Assurance Requirements for Control of Items and Services for Nuclear Power Plants."

With respect to ANSI N45.2.13, Section 3.2, "Content of the Procurement Documents," Subsection 3.2.3, "Quality Assurance Program Requirements," the licensee proposes to take the following exception:

> The requirements of this section are accepted with the following exception:
>
> When purchasing commercial-grade calibration services from calibration laboratories accredited by a nationally-recognized accrediting body, the procurement documents are not required to impose a quality assurance program consistent with ANSI N45.2-1971. Nationally-recognized accrediting bodies include the National Voluntary Laboratory Accreditation Program (NVLAP) administered by the National Institute of Standards and Technology (NIST) and other accrediting bodies recognized by NVLAP via a Mutual Recognition Agreement (MRA). In such cases, accreditation may be accepted in lieu of the Purchaser imposing a QA Program consistent with ANSI N45.2-1971, provided all the following are met:
>
> 1. The accreditation is to ANSI/ISO/IEC 17025.
>
> 2. The accrediting body is either NVLAP or an accrediting body recognized by NVLAP through an MRA.
>
> 3. The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
>
> 4. The purchase documents impose additional technical and administrative requirements, as necessary, to satisfy APS QA Program and technical requirements.
>
> 5. The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.

The NRC staff finds the proposed exception acceptable with the following clarifying bases:

- With respect to the term "MRA," the proposed exception should be understood to mean "Mutual Recognition Arrangement," which is the accepted terminology.

- The NRC staff recognizes the Mutual Recognition Arrangement conferred by signatory status with the ILAC. However, the NRC staff's evaluation and approval are limited to NVLAP and to A2LA accreditation, which is recognized by NVLAP through the ILAC MRA.

- Items 3, 4, and 5 address differences between the licensee's currently approved approach and the ANSI/ISO/IEC 17025 approach, as discussed in Section 3.2.1 of this evaluation. Item 3 requires the supplier to provide a measurement of collective uncertainty and, therefore, obviates the need to impose the four-to-one ratio requirement discussed in NISTIR 6989. The technical and administrative requirements of item 4 shall explicitly impose NUPIC clause 14.1.c.7 (see Section 3.2.1 above), which requires that the calibration certificate/report include identification of the laboratory equipment/standards used.

3.4.3 Regulatory Guide 1.144

RG 1.144 (Reference 12) describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to auditing of QA programs for nuclear power plants. RG 1.144, Revision 1 conditionally endorses ANSI N45.2.12-1977, "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants."

With respect to RG 1.144, the licensee proposes to add the following interpretation:

> D. Regulatory Guide 1.144, Section C.3.b(2)
>
> The requirements of this section are accepted with the following interpretation:
>
> When purchasing commercial-grade calibration services from calibration laboratories accredited by a nationally-recognized accrediting body, the accreditation process and accrediting body may be credited with carrying out a portion of the Purchaser's duties of verifying acceptability and effective implementation of the calibration service supplier's quality assurance program.
>
> Nationally-recognized accrediting bodies include the National Voluntary Laboratory Accreditation Program (NVLAP) administered by the National Institute of Standards and Technology (NIST) and other accrediting bodies recognized by NVLAP via a Mutual Recognition Agreement (MRA).
>
> In lieu of performing an audit, accepting an audit by another licensee, or performing a commercial-grade supplier survey, a documented review of the supplier's accreditation shall be performed by the Purchaser. This review shall include, at a minimum, verification of all the following:

1. The accreditation is to ANSI/ISO/IEC 17025.

2. The accrediting body is either NVLAP or an accrediting body recognized by NVLAP through an MRA.

3. The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

The NRC staff finds the proposed interpretation to be acceptable under the applicable conditions stated in Section 3.4.2 above. The NRC staff notes that the licensee is responsible for ensuring that the procured services are within the accredited scope of the NVLAP and A2LA certificates.

3.4.4 Change to the Quality Assurance Program

Pursuant to the change provisions of 10 CFR 50.54(a)(4), the licensee proposes the following change to the QA Program described in Section 17.2 of the UFSAR:

D. The supplier is providing commercial-grade calibration services and is accredited by a nationally-recognized accrediting body as described in the APS responses to NRC Regulatory Guides 1.123 and 1.144 that are documented in Section 1.8 of the UFSAR. For suppliers of commercial-grade calibration services with accreditation by a nationally-recognized accrediting body, a documented review of the supplier's accreditation by the purchaser may be used in lieu of inspections or tests following delivery or in-process surveillances during performance of the service. This review shall include, at a minimum, all of the following:

   1. The accreditation is to ANSI/ISO/IEC 17025.

   2. The accrediting body is either NVLAP or an accrediting body recognized by NVLAP through an MRA.

   3. The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

The NRC staff finds the proposed change to be consistent with the foregoing stated positions with respect to regulatory guides and is, therefore, acceptable.

4.0 CONCLUSION

Based on review of the NVLAP program and observation of the NVLAP accreditation process, the NRC staff finds NVLAP accreditation to provide an acceptable alternative to a supplier audit, commercial-grade survey, or in-process surveillance for the qualification of commercial-grade calibration service suppliers. Based on review of the A2LA program and the ILAC Mutual Recognition Arrangement, whereby NVLAP recognizes the equivalence of A2LA accreditation, the NRC staff finds A2LA accreditation to also provide an acceptable alternative to the identified licensee qualification processes.

Based on review of the changes to the licensee's operational QA Program, the revised commitments to applicable regulatory guides, and the clarifying bases included in Section 3.4.2 above, the NRC staff concludes that the QA Program, described in Section 17.2 of the UFSAR, continues to satisfy the requirements of Appendix B to 10 CFR Part 50 and is, therefore, acceptable.

5.0 REFERENCES

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3. NRC Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," March 21, 1989.

4. NUPIC Document 29, "Commercial Grade Calibration Services Implementation Guidelines," Revision 1, June 21, 2000.

5. "NUPIC Commercial Grade Survey Checklist - Calibration Services," Revision 1.

6. NIST Handbook 150, "Procedures and General Requirements, National Voluntary Laboratory Accreditation Program," July 2001.

7. NIST Information Report NISTIR 6989, "Comparison of ANSI/ISO/IEC 17025 with the NUPIC Audit Checklist," May 2003.

8. NVLAP Assessment, Laboratory Code 200491, General Electric Infrastructure Sensing Laboratory, April 1, 2005.

9. PSEG Nuclear Oversight Survey Report SNA05-046, August 4, 2005.

10. Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operations)," Revision 2, February 1978.

11. Regulatory Guide 1.123, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants," Revision 1, July 1977.

12. Regulatory Guide 1.144, "Auditing of Quality Assurance Programs for Nuclear Power Plants," Revision 1, September 1980.

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